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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,209	08/24/2001	Pat Ressler Levitt	00-539-US	3394
7590	12/18/2003		EXAMINER	
Frederick H. Colen REED SMITH LLP P.O. Box 488 Pittsburgh, PA 15230-0488			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/939,209	LEVITT ET AL.
	Examiner	Art Unit
	Celine X Qian	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 September 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) 8-17,21-39,44 and 45 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7,18,19 and 40-43 is/are rejected.

7) Claim(s) 1-7,20 and 40-43 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 02 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1201,0903</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claims 1-45 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the response filed on 9/22/03 is acknowledged. Applicants further elected SEQ ID NO: 3, and mutation T at base number 4121 of SEQ ID NO: 3 for examination. The traversal is on the ground(s) that the invention does not recite a multiplicity of species so that it would be burdensome for the search. Applicants further argue that MPEP allows for a search of up to 10 sequences in a single invention. This is not found persuasive for same reasons set forth of the record mailed on 3/19/03. The nucleic acid of SEQ ID NO:3-8 are patentably distinct composition which does not render each other obvious, the search is not co-extensive. As discussed in the previous office action, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 8-17, 21-39 and 44-45 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-7, 18-20 and 40-43 are currently under examination.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 15, 16 and 42). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 1-7, 20 and 40-43 are objected to for containing non-elected subject matter. Amending the claims such that they are only directed to elected inventions is required.

Applicant is advised that should claim 2 be found allowable, claim 41 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

Claims 18 and 19 are rejected under 35 U.S.C. 101 because they are not directed to statutory subject matter. The claims encompass human subjects. It is PTO policy not to issue claims that encompass humans (see 1077 OG 24, April 21, 1987).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims recite SEQ ID NO:3 and contiguous portions thereof. SEQ ID NO:3 is the genomic sequence encoding human RGS4, a gene that is linked to schizophrenia. The specification teaches that 34 polymorphisms within the genomic sequence are linked to schizophrenia. In addition, a decrease in RGS4 expression is also found in schizophrenic patients. The contiguous sequence of SEQ ID NO:3 encompasses

Art Unit: 1636

a potentially large genus of nucleic acid sequences of various sizes that may not related to RGS4. They encompasses nucleic acid sequences either 5' or 3' to the RGS4 gene of various sizes which do not link to schizophrenia. The specification only discloses SEQ ID NO:3-8, the gene encoding RGS4, and five other genomic fragments within close proximity of the RGS4 gene that contain polymorphisms linked to schizophrenia. Thus, the specification fails to describe a representative number of species by their complete structure or other identifying characteristics. Therefore, the written description requirement is not met.

Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with an expression vector comprising SEQ ID NO:3, does not reasonably provide enablement for human or transgenic animals comprising SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The nature of the invention is an expression system comprising a DNA sequence corresponding to SEQ ID NO:3. The claims are further drawn to an expression system comprising a host cell transformed with SEQ ID NO:3.

The breadth of the claims is broad. The claims encompass human, transgenic animal and host cell comprising a DNA sequence corresponding to SEQ ID NO:3.

The teaching of the specification is limited. The specification only enables the scope of a host cell comprising an expression vector comprising SEQ ID NO:3. The specification fails to teach any transgenic animal that comprising SEQ ID NO:3 in its genome. The specification further fails to teach a phenotype that is associated with transgenic animal comprising the nucleic

acid sequence of SEQ ID NO:3. (As discussed above, human subject is not statutory subject matter under 35 USC 101.)

The state of art at the time of filing teaches that making a transgenic animal with predicted phenotype as highly unpredictable. The phenotype of the transgenic animal is a required element for the enablement of the claimed invention because one would not know how to use the transgenic animal without any phenotype. Since the instant specification does not teach how to make a transgenic animal with predicted phenotype, nor does the specification provides any working example of a transgenic animal with a specific phenotype, one of skilled in the art would have to engage in undue experimentation to make and use the claimed invention. Therefore, the claims are not enabled to their full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “the contiguous portion of SEQ ID NO:3 contains a variation ... a T at nucleotide base number 4121 of SEQ ID NO: 3” renders the claim indefinite because it is unclear where the mutation is. In other words, nucleotide base number 4121 is within SEQ ID NO: 3, not in its contiguous portion. Clarification is required.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER